



Food and Drug Administration
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April 24, 2015

Nihon Kohden Corporation
% Natalie Kennel
Regulatory Affairs Consultant
NJK & Associates Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K142624
Trade/Device Name: Neuromaster G1 Mee2000
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, IKN, ETN, GWQ, JXE, GZO, GWF, and GWJ
Dated: March 20, 2015
Received: March 25, 2015

Dear Ms. Kennel,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K142624 Page 1 of 3

Device Name

Neuromaster G1 MEE2000 Neural Function Measuring System

Indications for Use (Describe)

The Neuromaster G1 MEE 2000 Neural Function Measuring System is intended to monitor, record, and display the bioelectric signals produced by sensory and motor pathways in the operating room, critical care, and other areas where continuous monitoring is needed. The system measures and displays electric/auditory/visual evoked potential (EP), electroencephalography (EEG), and electromyography (EMG), skin temperature of distal portion of extremities, SpO₂, and ETCO₂ to provide health care professionals with information to help assess a patient's neurological status. The system is used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders and used for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

- EEG - The device may also measure and record the electrical activities of the patient's brain obtained by placing two or more electrodes on the head (EEG).
- EP-Electrical/ Auditory/ Visual - Continuous and/or periodic measurements of evoked potential activities are displayed and stored. The device applies an electrical stimulus to a patient through commercially available skin electrodes for the purpose of measuring the evoked response. The photic stimulator is used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye and the auditory stimulator produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Indications for Use

510(k) Number (if known)
K142624 page 2 of 3

Device Name
Neuromaster G1 MEE2000 Neural Function Measuring System

Indications for Use (Describe)

- Free Run EMG - The Free Run EMG function identifies spontaneous EMG activity of nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.
- CoMEP - Cortical stimulation techniques for cortical mapping are used at "Low Output" for placement of electrodes during surgical procedures and for brain mapping during treatment of patients with seizure disorders.
- TcMEP - Transcranial electrical stimulation techniques for motor evoked potentials (TcMEP) are used at "TcMEP Output" for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency."
- Nerve conduction study - The device is intended to measure and display nerve conduction time by applying a stimulus to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.
- SpO2 - When the SpO2 adapter and finger and toe probe for SpO2 measurement are used, oxygen saturation information is automatically measured and displayed.
- EtCO2 - When the CO2 adapter and sensor for EtCO2 measurement are used, end-tidal carbon dioxide of respiratory gas information is automatically measured and displayed.
- Skin temperature - When the skin temperature sensor for skin temperature measurement is used, skin temperature information is automatically measured and displayed.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
K142624 page 3 of 3

Device Name
Neuromaster G1 MEE2000 Neural Function Measuring System

Indications for Use (Describe)

- Remote reader – The remote reader function provides real time remote access to the system for a monitoring physician outside of the operating room.

The system is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional.

The system is available for use on any patient as determined by the medical professional including adults and children of all ages.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

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Date Prepared: April 22, 2015

DEVICE INFORMATION

Proprietary Name: Neuromaster G1 MEE2000 System
Common Name: Neural Function Measuring System
Classification: Class II (Performance Standards)
Device Product Code & Classification Panel:

Panel: Neurology
21 CFR 890.1375 product code IKN
21 CFR 874.1820 product code ETN
21 CFR 882.1400 product code GWQ
21 CFR 882.1550 product code JXE
21 CFR 882.1540 product code GZO
21 CFR 882.1870 product code GWF
21 CFR 882.1890 product code GWJ

Predicate Devices:

The predicate devices are listed in Table 1. The main predicate device is the Neuromaster MEE1000 System and the other two are additional reference predicates.

None of the predicates have been subject to design recalls.

Table 1 Table of Predicates

510(k)	Product	510(k) Holder
K051178	Neuromaster MEE1000 Neural Function Measuring System	Nihon Kohden America, Inc
K962455	Cadwell Cascade	Cadwell Laboratories
K040358	XLTEK	Excel Tech LTD
K050798 & K061173	Eclipse Neurological Workstation	Formerly Axon Systems, Inc. Now Medtronic Xomed
K053363 (K850342)	Subdural Electrodes	AD-Tech
K071969	SEN-4100A Electric Stimulator	Nihon Kohden Corporation
K083124	Nerve Integrity Monitor 3.0	Medtronic Xomed
K110410	MS-120BK Electrical Stimulator	Nihon Kohden America, Inc.
K111647	C2 Nerve Monitor System	Inomed
K112718	NVM5 System	NuVasive
K120397	MEB-2300A	Nihon Kohden America, Inc.

Product Description:

The Neuromaster G1 MEE2000 Neural Function Measuring System is a compact and multi-functional system for continuous monitoring of brain and neural pathways intraoperatively and in critical care areas. The system measures and displays electric/auditory/visual evoked potential (EP), electroencephalography (EEG), and electromyography (EMG), skin temperature of distal portion of the extremities, SpO₂, and ETCO₂. The system also measures and displays nerve conduction time by applying a stimulus to a patient's peripheral nerve. The system includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

The system uses electrical stimulus, visual stimulus, or sound stimulus in evoked responses measurements (EP). Continuous and/or periodic measurements of evoked potential activities are displayed and stored. The system applies an electrical stimulus to a patient through skin electrodes for the purpose of measuring the evoked response. The photic stimulator is used to generate and display a shifting light pattern or to apply a brief light stimulus for use in evoked response measurements or electroencephalogram activation. The system may measure and record the electrical activities of the patient's brain obtained by placing two or more electrodes on the head (EEG).

The system can be used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders and used for intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction

brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

The system can be connected to SpO₂ and ETCO₂ sensors to display the patient's oxygen saturation values as measured by pulse oximetry and CO₂ values respectively throughout the procedure.

The acquired waveforms are displayed in cascaded format and measurement data may be displayed on the trend graph with waveform annotations (events). The acquired waveforms with the measurement data can be saved to a large capacity storage media. The data can be printed directly on paper, printed to portable document format (pdf), and/or archived to other locations.

The Neuromaster G1 MEE2000 System consists of at minimum a main unit (DC-200B), an amp unit (JB-232B), one breakout box (JB-210B), four stimulation pods [JS-201B(A), JS-202B (B), JS-203B (C), JS-204B (D)], and a computer (CC-201BK) with specific software. There are several standard and optional accessories such as cables, connectors, SpO₂ probes, ETCO₂ sensors, and various types of electrodes and leads.

A complete list of all modalities/software functions of the Neuromaster G1 MEE2000 System is given in Table 2.

Table 2 MEE2000 Modalities/Software Functions

- Electrical Evoked Potentials
 - Somatosensory Evoked Potentials (SEP)
 - Short-Latency Somatosensory Evoked Potential (SSEP)
 - Spinal cord evoked potentials (SCEP) (or ESCP: evoked spinal cord potential)
 - Electric Customizable
- Auditory Evoked Potentials
 - Auditory Brainstem Response (ABR)
 - Middle Latency Response (MLR)
 - Slow Vertex Response (SVR)
 - Electrocochleography (EcochG)
 - Auditory Customizable
- Visual Evoked Potentials
 - Pattern Reversal Visual Evoked Potential (PR-VEP)
 - Goggle Visual Evoked Potential (LED goggle -VEP)
 - Flash Visual Evoked Potential (Flash-VEP)
 - Electroretinography (ERG)
 - Visual Customizable
- Electromyography (EMG)
 - Free-run EMG
- Electroencephalography (EEG)
 - Electroencephalography (EEG)
 - Density Spectral Array (DSA)
 - Compressed Spectral Array (CSA)
- Nerve Conduction
 - Motor Nerve Conduction studies (MCS)

- Sensory Nerve Conduction studies (SCS)
- Trend Monitoring
 - Trend-ABR
 - Trend-SEP
 - Trend-VEP
 - Trend-DSA
 - Trend-CSA
- Motor Evoked Potential (MEP)
 - Transcranial Motor Evoked Potential (TcMEP)
 - Cortical Motor Evoked Potential (CoMEP)
- Remote Monitoring

Indications for Use

The Neuromaster G1 MEE 2000 Neural Function Measuring System is intended to monitor, record, and display the bioelectric signals produced by sensory and motor pathways in the operating room, critical care, and other areas where continuous monitoring is needed. The system measures and displays electric/auditory/visual evoked potential (EP), electroencephalography (EEG), and electromyography (EMG), skin temperature of distal portion of extremities, SpO₂, and ETCO₂ to provide health care professionals with information to help assess a patient's neurological status. The system is used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders and used for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

- EEG - The device may also measure and record the electrical activities of the patient's brain obtained by placing two or more electrodes on the head (EEG).
- EP-Electrical/ Auditory/ Visual - Continuous and/or periodic measurements of evoked potential activities are displayed and stored. The device applies an electrical stimulus to a patient through commercially available skin electrodes for the purpose of measuring the evoked response. The photic stimulator is used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye and the auditory stimulator produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.
- Free Run EMG - The Free Run EMG function identifies spontaneous EMG activity of nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.
- CoMEP - Cortical stimulation techniques for cortical mapping are used at "Low Output" for placement of electrodes during surgical procedures and for brain mapping during treatment of patients with seizure disorders.
- TcMEP - Transcranial electrical stimulation techniques for motor evoked potentials (TcMEP) are used at "TcMEP Output" for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

- Nerve conduction study - The device is intended to measure and display nerve conduction time by applying a stimulus to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.
- SpO2 - When the SpO2 adapter and finger and toe probe for SpO2 measurement are used, oxygen saturation information is automatically measured and displayed.
- EtCO2 - When the CO2 adapter and sensor for EtCO2 measurement are used, end-tidal carbon dioxide of respiratory gas information is automatically measured and displayed.
- Skin temperature - When the skin temperature sensor for skin temperature measurement is used, skin temperature information is automatically measured and displayed.
- Remote reader – The remote reader function provides real time remote access to the system for a monitoring physician outside of the operating room.

The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional.

The device is available for use on any patient as determined by the medical professional including adults and children of all ages.

Comparison to Predicate Devices

Table 3 contains a comparison of the Neuromaster G1 MEE2000 System to its main predicate device, the Neuromaster MEE1000 System and additional “reference” predicates to support certain aspects in this comparison. Table 4, Table 5, Table 6, Table 7, and Table 8 have been included to completely describe the substantial equivalence comparison of the detailed functional aspects of the Neuromaster G1 MEE2000 to its predicates. Table 9 contains a detailed comparison of the new Neuromaster G1 MEE2000 NCS Electrode to the predicate electrode to support the physical, patient contact and material aspects in this comparison.

Table 3 Substantial Equivalence Table for Neuromaster G1 MEE2000 System

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Indications for Use	<p>The Neuromaster G1 MEE 2000 Neural Function Measuring System is intended to monitor, record, and display the bioelectric signals produced by sensory and motor pathways in the operating room, critical care, and other areas where continuous monitoring is needed. The system measures and displays electric/auditory/visual evoked potential (EP), electroencephalography (EEG), and electromyography (EMG), skin temperature of distal portion of extremities, SpO₂, and ETCO₂ to provide health care professionals with information to help assess a patient's neurological status. The system is used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders and used for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.</p> <ul style="list-style-type: none"> • EEG - The device may also measure and record the electrical activities of the patient's brain obtained by placing two or more electrodes on the head (EEG). • EP-Electrical/ Auditory/ Visual - Continuous and/or periodic measurements of evoked potential activities are displayed and stored. The device applies an electrical stimulus to a patient through commercially 	<p>Nihon Kohden's model number MEE-1000 is intended for medical purposes to measure, monitor, record and display the bioelectric signals produced by muscles (EMG), to stimulate peripheral nerves and to monitor, record and display the electrical activities produced by nerves to aid clinicians in the diagnosis and prognosis of neuromuscular disease. The device monitors electric/auditory/visual evoked potential, EEG and EMG. The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time. The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). Continuous and/or periodic measurements of evoked potential activities are displayed and stored. The device applies an electrical stimulus to a patient thru commercially available skin electrodes for the purpose of measuring the evoked response. The photic stimulator is used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye and the auditory stimulator produces a sound stimulus for use in evoked response measurements or electroencephalogram activation. The device</p>	<p>The subject device has the same intended use as the main predicate device. The indications for use for the MEE2000 include two aspects that are covered by additional reference predicate devices: One is the inclusion of SpO₂ and EtCO₂ measurements which is also included in the Eclipse Neurological Workstation by Axon (K050798). The second is the inclusion of nerve stimulator at low output for surgical procedures and brain mapping during treatment of patients with seizure disorders and at high output to be used for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency. This second indication for use is covered by another reference predicate, MS120BK Electric Stimulator (K1110410). The MS120BK Electric stimulator was cleared to connect to the MEE1000 through its amplifier. In the subject device the capability is included.</p>

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Indications for Use, con't	<p>available skin electrodes for the purpose of measuring the evoked response. The photic stimulator is used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye and the auditory stimulator produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.</p> <ul style="list-style-type: none"> • Free Run EMG - The Free Run EMG function identifies spontaneous EMG activity of nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions. • CoMEP - Cortical stimulation techniques for cortical mapping are used at "Low Output" for placement of electrodes during surgical procedures and for brain mapping during treatment of patients with seizure disorders. • TcMEP - Transcranial electrical stimulation techniques for motor evoked potentials (TcMEP) are used at "TcMEP Output" for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency." • Nerve conduction study - The device is intended to measure and display nerve conduction time by applying a stimulus to a patient's peripheral nerve. This device includes the stimulator and the electronic 	<p>may be used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. The device may also measure and record the electrical activities of the patient's brain obtained by placing two or more electrodes on the head (EEG). The acquired waveforms are displayed in cascaded format and measurement data may be displayed on the trendgraph with waveforms annotations (events). The acquired waveforms with the measurement data can be saved in a large capacity storage media. The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device is available for use on any patient as determined by the medical professional including adults and children.</p>	See above

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Indications for Use, con't	<p>processing equipment for measuring and displaying the nerve conduction time.</p> <ul style="list-style-type: none"> • SpO2 - When the SpO2 adapter and finger and toe probe for SpO2 measurement are used, oxygen saturation information is automatically measured and displayed. • EtCO2 - When the CO2 adapter and sensor for EtCO2 measurement are used, end-tidal carbon dioxide of respiratory gas information is automatically measured and displayed. • Skin temperature - When the skin temperature sensor for skin temperature measurement is used, skin temperature information is automatically measured and displayed. • Remote reader – The remote reader function provides real time remote access to the system for a monitoring physician outside of the operating room. <p>The system is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional.</p> <p>The system is available for use on any patient as determined by the medical professional including adults and children of all ages.</p>	See above	See above

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Warnings/ Contraindications	Items related to off label use or misuse. Items related to design and indicated use limitations such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment Warnings regarding use of paralyzing agents and surgical severing of nerves Contraindication regarding use of TcMEP	Items related to off label use or misuse. Items related to design and indicated use limitations such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Most warnings and precautions are the same as MEE1000 Contraindication& Warnings same as Eclipse (K050798)
Intended Use Patient Population	The system is available for use on any patient as determined by the medical professional including adults and children of all ages.	The device is available for use on any patient as determined by the medical professional including adults and children	No difference
General System Approach	Computer based equipment with dedicated hardware peripherals/components	Computer based equipment with dedicated hardware peripherals/components	The specific peripherals/components are more compact for customer convenience
Input Boxes (Breakout boxes)	1, 2, 3 or 4 input boxes	1, 2 or 3 input boxes	Number of input pins is 1 higher, MEB-2300A (K12097).
Stimulation Pod	1, 2, 3 or 4 within low-level	1, 2, 3 or 4 and 1 or 2 at low-level	Number of units are reduced (The MEE2000 has 4 stimulation pods which are for both normal stimulation and low level stimulation whereas the MEE1000 has 4 stimulation pods for normal stimulation and 2 other stimulation pods for low level stimulation.)

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
TcMEP control Box	1	Option (SEN-4100A, MS-120Bk)	Built-in function in ME2000, see SEN-4100A (K071969), MS120BK (K110410)
Foot switch	Available	None	Foot switch for hands free use increases usability.
Computer Hardware/Software			
Operation System	WIN 7 Professional 32bit	WIN XP Pro	Depends on the PC (currently available computers)
Memory	4+ GB	1 GB RAM	Depends on the PC (currently available computers)
Network	10/100/1000 Mb/s Ethernet	Standard Ethernet interface	No difference
CPU	Core - i5, 2.0+ GHZ	Pentium M 760, 2.00 GHZ	Depends on the PC (currently available computers)
Storage capacity	250 + GB (7200 rpm)	40GB hard drive minimum	Depends on the PC (currently available computers)
Amplifiers			
Number of Channels	32 channels	16 or 32 channels	Two models are not needed. 16 channel is covered with 32 channel device. NVM5 (K112718) has 32 channels.

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Maximum number of connectable breakout boxes (maximum total number of input jacks)	4(64)	4(64)	No difference
Input Impedance	>100 M Ω (Differential Mode) \geq 1000 M Ω (Common Mode)	>100 M Ω (Differential Mode) \geq 1000 M Ω (Common Mode)	No difference
Noise	<4.5 μ V p-p or <0.6 μ Vrms (at 1Hz-3kHz input shorted)	<3 μ V p-p (1Hz-3kHz)	Subject device has slightly higher noise than main predicate but lower than other predicates including: Xltek (K040358), Eclipse (K050798), NVM5 (K112718).
Common Mode Rejection Ratio (CMRR)	\geq 106 dB (Balanced mode) \geq 112 dB (Isolation mode)	\geq 106 dB (Balanced mode) \geq 112 dB (Isolation mode)	No difference
Sensitivity	EP/ free-run waveform: 0.05 to 500 μ V/div and 1 to 50 mV/div EEG: 5 to 10000 μ V/div	EP/EMG: 0.05 to 500 μ V/div and 1 to 50 mV/div EEG: 5 to 10000 μ V/div	No difference (EMG and free run waveform – different terminology for same function)
Low-cut Filter	EP/ free-run waveform: 0.08 Hz to 3 kHz at 6 dB/octave EEG: 0.08 Hz to 159 Hz at 6 dB/octave Time constant: 0.001, 0.003, 0.03, 0.1, 0.3, 0.6, 1, 2 s	EP/EMG: 0.08 Hz to 500Hz at 6 dB/octave EEG: 0.08 Hz to 159 Hz at 6 dB/octave	New customer requested feature of 3kHz filter. New filter does not raise new issue of safety or effectiveness. MEB-2300A (K120397) has 3 kHz maximum.
High-cut Filter	EP/ free-run waveform: 10 Hz to 3 kHz at 12 dB/octave, off EEG: 15 Hz to 300 Hz at 12 dB/octave	EP/EMG: 10 Hz to 3 kHz at 12 dB/octave EEG: 15 Hz to 300 Hz at 12 dB/octave	No difference

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Skin Electrode contact Impedance Check	2, 5, 10, 20, 50, 100, 200 k Ω indication	2, 5, 10, 20, 50, 100, 200 k Ω indication	No difference
Amplitude Calibration	1 div	10, 100 μ V, 1, 10mV	Change of the expression.
AC Interface notch filter	50 or 60 Hz or Comb filter (Rejection ratio: <1/20)	50 or 60 Hz	New customer requested feature of Comb filter. New filter does not raise new issue of safety or effectiveness.
Electrode offset tolerance	> <u>±</u> 950mV	> 450mV	High depolarization voltage is required for waveform quality improvement
Other Physiological Monitoring			
Vital sign	Temperature, SpO ₂ , CO ₂	Temperature	New customer requested functionality of SpO ₂ & CO ₂ measurements. Additional reference predicate, Eclipse Neurological Workstation, K050798, has this functionality incorporated into a system with the intended use as the subject device
Vital sign measurement range	Temperature: 0 to 45 °C SpO ₂ : 0 to 100%SpO ₂ CO ₂ : 0 to 13.3 kPa (0 to 100 mmHg)	Temperature: 0 to 45 °C	New customer requested functionality of SpO ₂ & CO ₂ measurements. Additional reference predicate, Eclipse Neurological Workstation, K050798, has this functionality incorporated into a system with the intended use as the subject device
Averagers			
A/D Converter	18 bits (16- bit for stored data)	16 bits	Higher resolution is required by customers
Conversion Speed	5 μ s/channel max.	Same	No difference

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
EP Waveforms: Analysis time base:	0.2 ms/div to 1 s/div	EP/EMG: 5 ms/div to 1 s/div EEG: Same	New customer requested feature of longer time interval
EP Waveform Monitor Time Base or Display time (for EEG)	EP waveform: 5 ms/div to 1 s/div Free-run waveforms: 5 ms/div to 5 s/div EEG waveforms: 2 to 60 s/page	EP/EMG: 0.05 to 500 μ V/div and to 1 to 50 mV/div EEG: 100, 200, 500, 1, 2, 3 kHz	No difference – different expression
Sampling frequency	Free-run waveforms: 100, 200, 500 Hz, 1, 2, 5 kHz EEG waveform: 100, 200, 500 Hz, 1, 2 kHz	EP/EMG: 5 ms/div to 5 s/div EEG: Same	Expressed differently. New customer request feature of shorter time interval
Time Base Modes	Individually selected for each channel	Same	No difference
Trigger Delay Time	-10 to +10 div in 1 div steps or 0 to 500 ms	-10 to +10 div in 1 div steps	New customer requested feature of “ms” unit step.
Trigger Modes	Recurrent, Single Stim, Signal, EXT1, EXT2, Shift, Multi train, MTS from Train 1	Recurrent, Single, Signal, EXT1, EXT2	New customer requested additional trigger modes .
Trigger wave mode:	Single, Train, Train series (Multi train, Number of train: 2 to 7)	Single , Train	Single, Double, Train series (Multi train, Number of train 1 to 10) MEB- 2300A (K120397)
Number of Averages	1 to 9999	Same	No difference
Artifact Reject Inhibit Range	± 1 to ± 5 div or OFF	Same	No difference
Display			
Number of Waveform Traces	EP: 100,000/ch	10,000/ch	New customer requested feature to offer additional number of waveform traces per change
Waveform Display Modes	Monitor, Stimulate, Average	Monitor, Sweep, Analysis	Terminology difference only

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Cursors	2 horizontal, 2 vertical	2 horizontal, 2 vertical	No difference
Scale	5, 10, 15, 20 div	5, 10, 15, 20 div	No difference
Grid Display options	Broken line, Intersections, Vertical line, None	Line, Dot, OFF	Additional grid display options increase customer options and improve visual quality of information display
Stimulator Common Functions			
Stimulus Rates	0.1 Hz to 50 Hz	0.1 Hz to 50 Hz	No difference
Stimulation Delay Time	0 to 10 seconds in 0.1 ms steps	0 to 10 seconds	No difference
External trigger signal	Amplitude: >4 V (polarity selectable) Duration: > 10 μ s	Amplitude: >4 V (polarity selectable) Duration: > 10 μ s	No difference
Trigger signal output	Amplitude: 5 V (within $\pm 5\%$) Duration: 1, 5, 10 ms (within $\pm 20\%$)	Amplitude: 5 V (within $\pm 5\%$) Duration: 1, 5, 10 ms (within $\pm 20\%$)	No difference
Electrical Stimulators			
Output type	1 for high or low output, 1 for TcMEP output	2 for high or low output, 1 for TcMEP output (option)	TcMEP covered by MB-120BK (K110410)
Number of Outputs (Maximum total number of outputs)	High: 8 (32) Low: 2 (8) TcMEP: 1 (8 jacks)	10 (High), 1 (Low) and more 10 (High), 1 (Low) by option	Maximum 32 high outputs was requested by customers.
Output mode	Constant current or constant voltage	See additional predicates	Constant current – MS-120B (K110410) or constant voltage- SEN- 4100A (K07196)

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Stimulus Intensity	High output: 0 to 100 mA / 0 to 300V Low output: 0 to 15 mA / 0 to 100 V TcMEP: 0 to 250 mA / 0 to 1000 V	High output: 0 to 100 mA / 0-300V Low output: 0 to 10 mA / 0 to 30V or 0 to 15 mA(MS-120BK) by option TcMEP: 10 to 1000 V (SEN-4100A), 0 to 200 mA (MS-120BK) by option	New functionality for low output to go to 100 V and TcMEP at 250 mA TcMEP Cadwell Cascade (K962455) and Nerve Integrity Monitor 3.0 (K083124) have voltage to 100V for low output. C2 Nerve Monitor System (K111647) has 250 mA for TcMEP.
Stimulus Pulse Duration	0.05 to 1 ms	0.05 to 1 ms	No difference
Output polarity	Positive, Negative	Positive, Negative	No difference
Output phase	Monophasic, Biphasic, Alternating	Monophasic, Biphasic, Alternating	No difference
Safety Limitation	Less than 50mJ / pulse (with 1k Ω load)	Not applicable	This safety limitation was phrased to be consistent with the 50 mJ/pulse (with 1 k Ω load) requirement specified in the IEC standard
Safety Limitation Notes	The following settings are not available. Stimulation rate of more than 1 Hz for the TcMEP output Train numbers of more than 9 for the TcMEP output Alternating mode for the TcMEP output Output of more than 15 mA for the Low output Monophasic mode for the Low output	See Additional reference predicates	The output is limited to 15 mA for the Low output in the US to be aligned to the MS-120BK predicate.
Auditory Stimulators			
Output Type	Earphones, Headphones	Headphones	Earphones option increase usability.

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Stimulus Waveform	Click, Tone Burst	Same	No difference
Stimulus Phase (polarity)	Condensation (positive), Rarefaction (negative), Alternating	Same	No difference
Stimulus Intensity	0 to 135 dB SPL	Same	No difference
Contralateral White Noise Masking	0 to -50 dB, or OFF	0 to -40 dB, or OFF	Lower masking noise option is customer request
Click Pulse Duration	0.1 to 1 ms	Same	No difference
Tone Burst Frequency	50 Hz to 10 KHz	Same	No difference
Plateau Time of tone burst	0 to 100 cycles	0 to 1000 ms	Cycle setting ability improves usability, change of units only
Rise/Fall Time of tone burst	1 to 100 cycles	0.1 to 10 ms	Cycle setting ability improves usability, change of units only
Visual Stimulators			
Stimulus Modes	Pattern Reversal, LED Flash, External Visual Stimulation	Same	No difference
Patterns	Checkerboard	Checkerboard, Horizontal Bars, Vertical Bars	Removed Horizontal Bars, Vertical Bars based on customer input for usability
Number of Horizontal Divisions	4, 8, 16, 32, 64, 128	Same	No difference
LED Flash Pulse Duration	1 to 50 ms	10 ms	New functionality of adjustable pulse duration
Recorder			
Recording Mode	Hard Copy, Trend	Same	No difference

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
External Input Analog Input	1 V/div (8 channels, selectable)	1 V/div (8 channels, selectable)	No difference
Dimensions			
Main Unit	400 (W) x 63 (H) x 315 (D) mm 4.0 kg	340 (W) x 41 (H) x 355 (D) mm 2.3 kg	Main unit is larger due to inclusion of several other units.
Electrode Junction Box (Amp unit)	32 channels only: 250 (W) x 190 (H) x 75 (D) mm 2.0 kg	16 channels :160 (W) x 210 (H) x 84 (D) mm 2.0 kg 32 channels: 265 (W) x 210 (H) x 84 (D) mm 2.7 kg	New device is smaller and lighter than 32 channel predicate
Power Unit	The Main Unit includes Power Unit.	Same	No difference
Power Requirements			
Line Voltage	100 to 240 V AC	117 V AC	To support use worldwide
Line Frequency	50/60 Hz	Same	No difference
Power Input	1000 VA (DC-200B)	Less than 75 VA	Power input to support different new functionality. This does not raise any new issues of safety and has been tested to safety standards
Inrush current	30 A max/115 Vac, 60 A max/230 Vac (EMI capacitors excluded, cold start at 25°C)	Not determined	Note that this was not measured with the MEE1000 predicate because it was required by IEC 60601-1 3 rd edition.
Environment			
Operating Temperature	10 to 35 °C (50 - 95°F)	Same	No difference
Storage Temperature	-20 to +60 °C (-4 to +140°F)	-20 to +65 °C	Depend on the PC (small change based on PC)
Operating Humidity	30 to 80% (non-condensing)	20 to 80%	Depend on the PC (small change based on PC)

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
Storage Humidity	10 to 95%	20 to 80%	Increased convenience for product storage
Operating Atmospheric Pressure	10 to 35 °C (50 - 95°F)	Same	No difference
Storage Atmospheric Pressure	700 to 1060 hPa	Same	No difference
Protocols Available			
Electric evoked potential	SEP (somatosensory evoked potential) SSEP (short-latency somatosensory evoked potential) SCEP (Spinal cord evoked potential) (This is referred to as ESCP in clinical protocol used for preoperative examination.) ELECTRIC (customizable protocol)	SEP (somatosensory evoked potential) SSEP (short-latency somatosensory evoked potential) ESCP (Evoked Spinal Cord Potential) ELECTRIC (customizable protocol)	The only difference between “SCEP” and “ESCP” is terminology. The function is as the same as the predicate.
Auditory evoked potential	ABR (auditory brainstem response) MLR (middle latency response) SVR (slow vertex response) EcochG (electrocochleography) AUDITORY (customizable protocol)	ABR (auditory brainstem response) MLR (middle latency response) SVR (slow vertex response) AUDITORY (customizable protocol)	EcochG (electrocochleography) is added because it is one of common examinations techniques used for monitoring of auditory evoked potential and is available in MEB-2300A (K120397).
Visual evoked potential	Pattern-VEP (pattern reversal visual evoked potential) Goggle-VEP (LED goggle visual evoked potential) Flash-VEP (Flash visual evoked potential) ERG (Electroretinography) VISUAL (customizable protocol)	PR-VEP (pattern reversal visual evoked potential) LED-VEP (LED visual evoked potential) EXT-VEP (External flash stimulator visual evoked potential) ERG (Electroretinography) VISUAL (customizable protocol)	For Pattern-VEP, Goggle-VEP, Flash-VEP, the only difference from the predicate device is terminology. The function is as the same as the predicate.

Characteristic	Neuromaster G1 MEE2000 System (this submission)	Neuromaster MEE1000 System Nihon Kohden (K051178)	Comparison and additional reference predicates
EMG (electromyogram)	Free-run EMG	EMG (electromyogram) MUP (Motor unit action potential)	The only difference between “Free-run EMG” and “EMG” is terminology. The function is as the same as the predicate. Free-run EMG is referred to as “Free-run waveform” in the Operator’s Manual. MUP is removed from MEE-2000 because it is not necessary.
Nerve Conduction	MCS (motor nerve conduction studies) SCS (sensory nerve conduction studies)	MCS (motor nerve conduction) SCS (sensory nerve conduction) F-WAVE	F-wave is removed from MEE-2000 because of low frequency of use.
Autonomic Nervous System	None	SSR (Sympathetic skin response)	SSR is removed from MEE-2000 because of low frequency of use.
Trend Monitoring	Trendgraph (Trend ABR or/and SEP or/and VEP) Trend CSA/DSA	Trend-ABR Trend-SEP Trend-VEP CSA	DSA is added, which is different expression of CSA.
EEG	EEG (Electroencephalography) DSA (Density Spectral Array) CSA (Compressed Spectral Array)	EEG (Electroencephalography) CSA (Compressed Spectral Array)	DSA is added, which is different expression of CSA.
Motor Evoked Potential (MEP)	Transcranial Motor Evoked Potential (TcMEP) Cortical Motor Evoked Potential (CoMEP)	Optional unit	MS-120BK (K110410) for TcMEP (Constant Current) and CoMEP and SEN-4100A (K071969)
Remote Monitoring	Remote Reader	None	Remote reader function is available in NVM5 (K112718)

Table 4 EMG Predicate Comparison Table

Specification/Property	Subject Device (K142624)	Predicate Device MEE-1000A (K051178)	Comment
Purpose	Free-run waveform	Free-run waveform	Same
Audible EMG	Yes	Yes	Same
Automatic Muting During Artifact	No	No	Same

Table 5 TcMEP (Constant Current) Predicate Comparison Table

Parameter	Subject Device (K142624)	Predicate Device MS-120B (K110410)	Comments
Purpose	TcMEP	TcMEP	Same
Stimulator Output			
Constant Current/Constant Voltage	Constant Current	Constant Current	Same
Maximum Current (mA)	250 (mA)	200 (mA)	Even if 250mA is applied, the energy per pulse is limited to maximum 50mJ.
Maximum Voltage (V @ 1k Ω load)	250 (V)	200 (V)	This is calculated by the maximum current 250mA.
Maximum Pulse Duration (ms)	1 (ms)	1 (ms)	Same
Waveform (ex. Rectangular monophasic)	Rectangular monophasic	Rectangular monophasic	Same
Output Frequency (Hz)	1 (Hz)	1 (Hz)	Same
Number of pulse trains	5	5	Same
Interpulse Interval (ms)	2 (ms)	1 (ms)	See SEN-41000A (K071969) for 2 ms
Energy per Pulse (mJ @ 1k Ω load)	50 (mJ)	40 (mJ)	The maximum safe energy recommendation of 50 mJ is put forth by IEC 60601-2-40.

Parameter	Subject Device (K142624)	Predicate Device MS-120B (K110410)	Comments
Maximum RMS Current (mA)	7.1 (mA)	6.3 (mA)	This is calculated by the maximum current 250mA.
Minimum Surface Area Electrode (cm ²)	0.5 (cm ²) surface electrode NM-413B (NKC)	0.5 (cm ²) surface electrode NM-413B (NKC)	Same
Maximum RMS Current Density (mA/cm ²)	14.1 (mA/cm ²)	12.7 (mA/cm ²)	This is calculated by the maximum current 250mA.
Maximum Charge Density (μC/cm ²)	Coulomb = Current x Time = 200 (uC) Charge Density= Coulomb / Area = 400 (μC/cm ²)	Coulomb = Current x Time = 200 (uC) Charge Density= Coulomb / Area = 400 (μC/cm ²)	Same
Maximum power density (W/cm ² @ 1 kΩ load)	W = Current x Voltage = 62.5 (W) Power Density = Watt / Area = 125 (W/cm ²)	W = Current x Voltage = 40 (W) Power Density = Watt / Area = 80 (W/cm ²)	This is calculated by the maximum current 250mA.
Interface			
Trigger Input	2	2	Same
Trigger Output	2	2	Same
Foot Switch Control	Sequence Start/Stop	Sequence Start/Stop	Same

Table 6 TcMEP (Constant Voltage) Predicate Comparison Table

Parameter	Subject Device (K142624)	Predicate Device SEN-4100A (K071969)	Comments
Purpose	TcMEP		
Stimulator Output			
Constant Current/Constant Voltage	Constant Voltage	Constant Voltage	Same
Maximum Voltage (V)	1000 (V)	1000 (V)	Same
Maximum Current (mA @ 1kΩ load)	1000 (mA)	1000 (mA)	Same
Maximum Pulse Duration (ms)	0.05 (ms)	0.05 (ms)	Same
Waveform (ex. Rectangular monophasic)	Rectangular monophasic	Rectangular monophasic	Same
Output Frequency (Hz)	1 (Hz)	1 (Hz)	Same
Number of pulse trains	5	5	Same
Interpulse Interval (ms)	2 (ms)	2 (ms)	Same
Energy per Pulse (mJ @ 1kΩ load)	50 (mJ)	50 (mJ)	Same
Maximum RMS Current (mA @ 1kΩ load)	7.1 (mA)	7.1 (mA)	Same
Minimum Surface Area Electrode (cm²)	0.5 (cm²) surface electrode NM-413B (NKC)	0.5 (cm²) surface electrode NM-413B (NKC)	Same
Maximum RMS Current Density (mA/cm² @ 1kΩ load)	14.1 (mA/cm²)	14.1 (mA/cm²)	Same
Maximum Charge Density (µC/cm² @ 1kΩ load)	Coulomb = Current x Time = 50 (uC) Charge Density= Coulomb / Area = 100 (µC/cm²)	Coulomb = Current x Time = 50 (uC) Charge Density= Coulomb / Area = 100 (µC/cm²)	Same

Parameter	Subject Device (K142624)	Predicate Device SEN-4100A (K071969)	Comments
Maximum power density (W/cm ² @ 1 kΩ load)	$W =$ Current x Voltage = 1000 (W) Power Density = Watt / Area = 2000 (W/cm ²)	$W =$ Current x Voltage = 1000 (W) Power Density = Watt / Area = 2000 (W/cm ²)	Same
Interface			
Trigger Input	2	1	Same as MS-120BK (K110410), MEE-1000A (K051178)
Trigger Output	2	1	Same as MS-120BK (K110410), MEE-1000A (K051178)
Foot Switch Control	Sequence Start/Stop	Sequence Start/Stop	Same

Table 7 Electrical (Low) EP Predicate Comparison Table

Parameter	Subject Device (K142624)	Predicate Device MS-120B (K110410)	Comments
Purpose	Facial, CoMEP	Facial, CoMEP	Same
Stimulator Output			
Constant Current/Constant Voltage	Constant Current	Constant Current	Same
Maximum Current (mA)	15 (mA)	15 (mA)	Same
Theoretical Max Voltage for System (V)	100 (V)	100 (V)	Same
Maximum Voltage at requested Impedances (V @ 1kΩ load)	15 (V)	15 (V)	Same
Maximum Pulse Duration (ms)	0.3 (ms)	0.3 (ms)	Same
Waveform (ex. Rectangular monophasic)	Rectangular biphasic	Rectangular biphasic	Same

Parameter	Subject Device (K142624)	Predicate Device MS-120B (K110410)	Comments
Maximum Output Frequency (Hz)	50 (Hz)	50 (Hz)	Same
Energy per Pulse (mJ @ 1kΩ load)	0.07 (mJ)	0.07 (mJ)	Same
Maximum RMS Current (mA)	0.3 (mA)	0.3 (mA)	Same
Minimum Surface Area Electrode (cm ²)	0.04cm ² Strip and grid electrode TS04R-SP10X-000 (Ad-Tech)	0.04cm ² Strip and grid electrode TS04R-SP10X-000 (Ad-Tech)	Same
Maximum RMS Current Density (mA/cm ²)	6.5 (mA/cm ²)	6.5 (mA/cm ²)	Same
Maximum Charge Density (μC/cm ²)	Coulomb = Current x Time = 4.5 (uC) Charge Density= Coulomb / Area = 113 (μC/cm ²)	Coulomb = Current x Time = 4.5 (uC) Charge Density= Coulomb / Area = 113 (μC/cm ²)	Same
Maximum power density (W/cm ² @ 1 kΩ load)	W = Current x Voltage = 0.23 (W) Power Density = Watt / Area = 5.63 (W/cm ²)	W = Current x Voltage = 0.23 (W) Power Density = Watt / Area = 5.63 (W/cm ²)	Same
Interface			
Trigger Input	2	2	Same
Trigger Output	2	2	Same
Foot Switch Control	Sequence Start/Stop	Sequence Start/Stop	Same

Table 8 Electrical EP (high) Predicate Comparison Table

Parameter	Subject Device (K142624)	Predicate Device MEE-1000A (K051178)	Comments
Purpose	SSEP		
Stimulator Output			
Constant Current/Constant Voltage	Constant Current	Constant Current	Same
Maximum Current (mA)	100 (mA)	100 (mA)	Same
Theoretical Max Voltage for System (V)	300 (V)	300 (V)	Same
Voltage at requested Impedances (V @ 1k Ω load)	100 (V)	100 (V)	Same
Maximum Pulse Duration (ms)	1 (ms)	1 (ms)	Same
Waveform (ex. Rectangular monophasic)	Rectangular Monophasic	Rectangular Monophasic	Same
Output Frequency (Hz)	50 (Hz)	50 (Hz)	Same
Energy per Pulse (mJ @ 1k Ω load)	10 (mJ)	10 (mJ)	Same
Maximum RMS Current (mA)	3.2 (mA)	3.2 (mA)	Same
Minimum Surface Area Electrode (cm ²)	0.5. (cm ²) Disc electrode NE-136B (NKC)	0.5 (cm ²) Disc electrode NE-136B (NKC)	Same
Maximum RMS Current Density (mA/cm ²)	6.4 (mA/cm ²)	6.4 (mA/cm ²)	Same

Parameter	Subject Device (K142624)	Predicate Device MEE-1000A (K051178)	Comments
Maximum Charge Density($\mu\text{C}/\text{cm}^2$)	Coulomb = Current x Time = 100 (μC) Charge Density= Coulomb / Area = 200 ($\mu\text{C}/\text{cm}^2$)	Coulomb = Current x Time = 100 (μC) Charge Density= Coulomb / Area = 200 ($\mu\text{C}/\text{cm}^2$)	Same
Max Power Density (W/cm^2)	W = Current x Voltage = 10 (W) Power Density = Watt / Area = 20 (W/cm^2)	W = Current x Voltage = 10 (W) Power Density = Watt / Area = 20 (W/cm^2)	Same
Interface			
Trigger Input	2	2	Same
Trigger Output	2	2	Same
Foot Switch Control	Sequence Start/Stop	Sequence Start/Stop	Same

Table 9 Substantial Equivalence Table for New Electrodes

	MEE2000 NCS Electrodes (New in Submission)	Predicate NCS Electrode MEB-2300A (K120397)	
Characteristic	NM-316Y	NM-317Y3	Comparison
Manufacturer	NKC	NKC	No difference
Description	2 x recording electrode (red) 2 x recording electrode (black) 1 x grounding electrode (green)	1 x recording electrode (red) 1 x recording electrode (black) 1 x grounding electrode (green)	Only available as 2 instead of 1
Cable length	0.2m	0.2m	No difference
Quantity	50 (5 x 10 packages) (5 electrodes/sheet)	30 (3 x 10 packages) (3 electrodes/sheet)	Quantity differences in packaging
Patient Contact	Yes: Gel part	Yes: Gel part	No difference
Single Use/Reusable	Single use	Single use	No difference
Provided Sterile	No	No	No difference
End user sterilization?	No	No	No difference
Color additives	Used in Connector part. No patient contact	Used in Connector part. No patient contact	No difference
Electrode withstand Voltage	within +/-30mV	within +/-30mV	No difference
Electrode impedance	10Hz, 3k Ω or less	10Hz, 3k Ω or less	No difference
Offset fluctuation and internal noise	within +/-150 μ (p-p)(5min)	within +/-150 μ (p-p)(5min)	No difference
Material	Gel cover: paper, Tape: polyethylene Gel: Acrylic hydrophilic macromolecule, glycerin, sorbitol, water Label: polyester non-woven fabric tape, acrylic (adhesive), Electrode element: Ag/AgCl and Ag/AgCl carbon, Electrode lead: Copper (core), PVC (covering) Connector: Phosphor bronze (core) PP (housing)	Gel cover & ID label: paper, Tape: polyethylene Gel: Acrylic hydrophilic macromolecule, glycerin, sorbitol, water Label: polyester non-woven fabric tape, acrylic (adhesive), Electrode element: Ag/AgCl and Ag/AgCl carbon, Electrode lead: Copper (core), PVC (covering) Connector: Phosphor bronze (core) PP (housing)	Patient contact part of NM-316Y (gel) is identical to predicate NM- 317Y3 so biocompatibility certificate provided

None of the performance or technological differences between the Neuromaster G1 MEE2000 System and its predicates raise any new issues of safety and effectiveness.

Performance Testing

The Neuromaster G1 MEE2000 System has been subjected to design verification and validation testing for electrical safety, electromagnetic compatibility, software V&V, operational performance, usability, and operational and storage environmental performance. These tests verified and validated the proper operation of the system. Conformance to 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables was met with compliance to IEC 60601-1 3rd edition clause 8.5.2.3.

Like its predicate, the Neuromaster G1 MEE2000 System is provided non-sterile and is not patient contacting. All patient contacting accessories but one electrode are previously cleared either Nihon Kohden products or other manufacturers' products so additional biocompatibility, shelf-life or if applicable sterilization validation was not necessary. A biocompatibility certificate was provided for the new electrode which was made of identical materials and process to a predicate.

No animal or clinical studies were necessary for Neuromaster G1 MEE2000 Neural Function Measuring System.

Conclusion:

The data and information provided in this submission support the conclusion that the Neuromaster G1 MEE2000 Neural Function Measuring System is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.